

## REMARKS

Continued examination is requested under 37 C.F.R. 1.114 in response to the final Office Action dated July 14, 2004.

### I. Cosmetic Preparation Claims 16 to 20

Cosmetic preparation claims 16 to 20 were rejected as obvious under 35 U.S.C. 103 (a) over "Antibacterial Properties of a Bioactive Glass" article by J. Allen, et al.

The final Office Action on page 3 in the "Response to Arguments" notes that applicants argue that the J. Allan, et al, reference **neither** discloses **nor** suggests the feature of selecting bioactive glass particles with an index of refraction that matches that of a liquid cosmetic composition to which it is added. This argument only applies to claims 16 to 20. However there is no rebuttal in the Office Action of this argument against the case of *prima facie* obviousness of claims 16 to 20 based on this argument. A reasonable explanation of the reasons for rejection of claims 16 to 20 as obvious over J. Allen is respectfully requested.

In view of the lack of reasons for rejection it is respectfully submitted that claims for a liquid cosmetic preparation in which bioactive glass particles are an effective antibacterial agent for preservation of the preparation and the bioactive glass particles match the index of refraction of the liquid cosmetic preparation are not *prima facie* obvious over the J. Allen, et al, reference.

Nevertheless independent cosmetic preparation claim 16 has been amended to further distinguish the claimed invention from the cited prior art. First, a particle size limit of 0.4 mm has been added and an upper limit for the amount of bioactive glass in the preparation has been added, namely up to 10 percent by weight. These limits have been added to provide a reasonable and definite upper limit to what is meant by "glass particle" and to provide a reasonable upper limit for the amount of bioactive glass in the cosmetic composition. In other words, the reason for adding these limits is to provide a claim wording that is as completely definite in its scope as possible. Basis for these limits is present in the last three paragraphs on page 4 of applicants' specification.

The other wording changes in claim 16 are related to patentability of the subject matter of claim 16 over the prior art. The limitation to an alcohol content insufficient for preservation has been reworded somewhat to make it clear that the claim covers compositions that contain no alcohol as well as those with very small amounts of alcohol that are insufficient to provide preservative action. Also the claim clearly states now that the amount of bioactive glass particles present is sufficient so that the bioactive glass particles act as a preservative. This latter statement was included because the concentration range in the first paragraph of claim 16 did not have a lower limit.

The amended claim 16 claims a preparation that is effectively protected from bacterial action by the bioactive glass particles but whose appearance is not impaired by the presence of the bioactive glass particles since they are not immediately visible to an observer using the preparation. Since most cosmetic

preparations are designed to appear appealing to the user, this is a great advantage for the cosmetic preparation, since it can be effectively protected without using toxic organic compounds by means of the bioactive glass, while at the same time retains its attractive appearance.

Applicants therefore respectfully request allowance of amended claims 16 to 20 for the cosmetic preparation with the invisible bioactive glass preservative agent.

For the foregoing reasons and because of the changes in claim 16, withdrawal of the rejection of claims 16 to 20 as obvious under 35 U.S.C. 103 (a) over J. Allen, et al, is respectfully requested.

## **II. Method Claims 10 to 15**

Method claims 10 to 15 were rejected as obvious under 35 U.S.C. 103 (a) over "Antibacterial Properties of a Bioactive Glass" article by J. Allen, et al.

Certainly applicants' "Background Section" in the specification teaches that the antibacterial action of bioactive glass is known and has had several applications in the prior art.

However the prior art has not previously recognized the great advantages of using bioactive glass particles of the smallest particle size in a range from 1 to 10  $\mu\text{m}$  and hence a large surface area, as disclosed by the applicants on page 4, next to last paragraph, of the English translation of the specification, especially in the case of cosmetic compositions that are applied to the skin. Because of the smaller particle sizes, smaller amounts of bioactive glass are effective and

provide good preservative action.

An unsigned Declaration containing comparative experimental evidence showing the unexpected advantages of using bioactive glass particles with a smaller particle size of 2  $\mu\text{m}$  in comparison to bioactive glass particles with a larger particles size accompanies this amendment. A signed copy of the Declaration will be obtained from the applicants and filed as soon as possible.

Particularly the evidence in the Declaration shows that significantly more of some bacteria are effectively eliminated after exposure to the bioactive glass particles of the smaller particle size after 2 days. In the case of one bacteria species, *Aspergillus Niger*, the bacterial count in an aqueous preparation containing 1 % bioactive glass particles having an average diameter  $d_{50}$  of 4  $\mu\text{m}$  is not significantly reduced two days after inoculation. However in the case of an aqueous preparation containing bioactive glass particles having an average diameter of 2  $\mu\text{m}$  the bacterial count for this species is reduced to 10 % 2 days after inoculation.

These results show that complete elimination or preservation with respect to **all** types of bacteria requires use of the smaller particle sizes at 1 % concentration levels. Surprisingly even with particle sizes down to about 4  $\mu\text{m}$  a significant bacterial count remains for a few bacterial species for a week or more after inoculation in an aqueous preparation containing 1 % bioactive glass.

These results clearly show that the finest particles sizes for the bioactive glass particles are more universally inhibiting of bacterial growth of a wide variety of bacterial species and thus unexpectedly better than the larger particle sizes,

such as those used by J. Allen (see page 2, first paragraph, of the English translation of the specification). The current obviousness rejection of pending claims in this application based on the J. Allen article, which describes bacterial inhibition experiments using bioactive glass having a particle size of 355 to 500  $\mu\text{m}$ , which of course are much larger. Applicants' experimental results in the Declaration suggest that bioactive glass with these larger particles sizes would not be immediately effective against contamination by *A. Niger* or else much larger amounts of the bioactive glass would be necessary.

Also it is well to remember that a claimed composition need only be unexpectedly better than the prior art with respect to a single property (M.P.E.P. 716.02 (a) I and II) to overcome a case of *prima facie* obviousness under 35 U.S.C. 103 (a). In the case of the instant application that single property is inhibition of growth of *A. Niger* (possibly also *C. albicans*).

Claims 10 to 15 have been amended to limit patent claim coverage to compositions or preparations containing the smaller-sized bioactive glass particles with particle sizes of 5 $\mu\text{m}$  or less. Claim 10 has been limited to particle sizes of 5 $\mu\text{m}$  or less. Claim 12 is further limited to particles sizes of 2 $\mu\text{m}$  or less. Claim 10 is limited to compositions containing 7 percent or less of the bioactive glass particles. Claim 12 is further limited to compositions containing 3 percent or less of the bioactive glass particles.

Thus it is respectfully submitted that this comparative experimental evidence is sufficient to overcome the case of *prima facie* obviousness of the amended claims 10 to 15 based on the J. Allen article, which describes results

only for larger sized particles with a particle size of 355 to 500  $\mu\text{m}$ .

For the foregoing reasons and because of the claim changes, withdrawal of the rejection of claims 10 to 15 as obvious under 35 U.S.C. 103 (a) over J. Allen, et al, is respectfully requested.

### **III. New Preparation Claims 21 to 24**

New cosmetic or pharmaceutical preparation claims have been limited to compositions that are applied to the skin (claim 21). Claim 24 further limits the compositions to make-up, lipstick, lotion applied to the skin or cream applied to the skin. These compositions, like the compositions claimed in claim 10, have been limited to compositions containing the smaller-sized bioactive glass particles in effective amounts up to about 7 % by weight.

Furthermore claim 21 includes the negative limitation that no organic chemical preservative compounds are present in addition to the bioactive glass particles. Basis for this limitation is found on page 5, first paragraph, of applicants' English translation of the specification. There is no suggestion in J. Allen, et al, that organic chemical preservative compounds should not be used in addition to the bioactive glass.

The compositions disclosed in J. Allen, et al, were not applied to the skin. J. Allen, et al, only performed model experiments performed culturing bacteria in liquid media, which has a composition similar to saliva.

The comparative evidence showing the unexpectedly better effectiveness of the smaller-sized particles having a particle size less than or equal to 5  $\mu\text{m}$  in

the accompanying Declaration supports composition as well as method claims for preparations containing the smaller sized bioactive glass particles of a size range less than 10  $\mu\text{m}$ . Accordingly preparation claims 21 to 24 have been added.

It is respectfully submitted that new claims 21 to 24 should not be rejected under 35 U.S.C. 103 (a) as obvious over J. Allen, et al.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,



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